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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,020	10/10/2000	Jennifa Gosling	19934000710	4696

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EXAMINER
BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/686,020	GOSLING ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to an isolated or recombinant CCX CKR polypeptide, classified in class 530, subclass 350.

II. Claim 5, drawn to a fusion protein comprising an isolated or recombinant CCX CKR polypeptide, classified in class 530, subclass 350.

III. Claims 6-14, drawn to an isolated polynucleotide that encodes a peptide, classified in class 536, subclass 23.1.

IV. Claims 15-19, drawn to an antibody that specifically binds a polypeptide, classified in class 530, subclass 387.1.

V. Claims 20-23, drawn to a method of detecting an CCX CKR gene product in a sample, classified in class 435, subclass 4.

VI. Claim 24, drawn to a method of amplifying a CCX CKR polynucleotide in a sample, classified in class 435, subclass 6.

VII. Claims 25-28, drawn to a method of identifying a modulator of the binding of CCX CKR to a chemokine, classified in class 435, subclass 7.1.

VIII. Claims 29-31, drawn to a method of identifying a modulator of CCX CKR activity, classified in class 435, subclass 4.

IX. Claims 33-36, drawn to a method of treating an CCX CKR-mediated condition in a mammal, classification dependent upon agent.

The inventions are distinct, each from the other because of the following reasons:

a. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I-IV are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the

protein of Group I can be prepared by processes which are materially different from recombinant DNA expression of Group III, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group III can be used other than to make the protein of Group I, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group I can be used in materially different methods other than to make the antibody of Group IV, such as in therapeutic or diagnostic methods (e.g., in screening). Finally, although the antibody of Group IV can be used to obtain the DNA of Group III, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The fusion protein of Group II is structurally different than the products of Groups I, II, and IV and can be used in methods other than to make the antibody of Group IV, such as *in vivo* diagnostic or treatment protocols.

b. Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons. Inventions V-IX are different methods because they require different ingredients, process steps, and endpoints. Groups V-IX are different methods requiring different method steps, wherein each is not required, one for another. For example, Invention V requires search and consideration of detection a CCX CKR gene product in a sample by contacting the sample with a probe and amplifying the gene product in the sample, which is not required by the other methods. Invention VI requires search and consideration of amplification of a CCX CKR polynucleotide in a sample by adding polymerase chain reaction reagents, two different primers, ligase chain reaction reagents, and two different oligomers, which is not required by the other inventions. Invention VII requires search and consideration of identification of a modulator of the binding of CCX CKR to a chemokine by contacting the CCX CKR polypeptide and the chemokine in the presence of a test

compound and measuring the level of binding between the chemokine and the polypeptide, which is not required by the other methods. Invention VIII requires search and consideration of identification of a modulator of CCX CKR activity by contacting a cell expressing the polypeptide and a test compound and assaying for a biological effect in the presence of the test compound, which is not required by the other methods. Invention IX requires search and consideration of efficacy of administration of an agent that modulates the activity or expression of CCX CKR in a cell or tissue in a mammal, which is not required by the other methods.

c. Inventions I and VII/VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used as an antigen for the production of antibodies..

d. Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in materially different processes, such as DNA purification or gene therapy.

e. Inventions II/IV and V/VI/VII/VIII/IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups II/IV and V/VI/VII/VIII/IX are unrelated products and methods, wherein each is

not required, one for another. For example, the claimed methods of Inventions V/VI/VII/VIII/IX do not recite the use or production of the fusion protein or antibody of Inventions II and IV, respectively.

f. Inventions III and V/VII/VIII/IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups III and V/VII/VIII/IX are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions V/VII/VIII/IX do not recite the use or production of the polynucleotide of Invention III.

g. Inventions I and V/VI/IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups I and V/VI/IX are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions V/VI/IX do not recite the use or production of the polypeptide of Invention I.

2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate search requirements, different classification, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method of detecting a CCX CKR gene product in a sample, wherein the gene product is:

a. a polypeptide

b. RNA

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-19, 22, and 24-36 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method of detecting a CCX CKR gene product in a sample by contacting the sample with a probe, wherein the probe is:

c. an antibody

d. a polynucleotide

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-19, 21, and 24-36 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for identifying a modulator of the binding of CCX CKR to a chemokine, wherein the chemokine is:

e. ELC

f. SLC

g. TECK

h. BLC

i. CTACK

j. mMIP-1γ

k. vMIPII

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-24, 27-32, and 35-36 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If Applicant selects Invention V, one species from the gene product group and one species from the probe group must be chosen to be fully responsive.

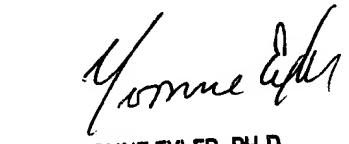
If Applicant selects Invention VII, one species from chemokine group must be chosen to be fully responsive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:00-5:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BEB
Art Unit 1647
June 17, 2002



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